



Senate

General Assembly

File No. 446

January Session, 2005

Substitute Senate Bill No. 934

Senate, April 20, 2005

The Committee on Judiciary reported through SEN. MCDONALD of the 27th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT PERMITTING STEM CELL RESEARCH AND BANNING THE CLONING OF HUMAN BEINGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2005*) (a) As used in this section
2 and sections 2 to 4, inclusive, of this act:

3 (1) "Institutional review committee" means the local institutional
4 review committee specified in 21 USC 360j(g)(3)(A)(i), as amended
5 from time to time, and, when applicable, an institutional review board
6 established in accordance with the requirements of 45 CFR 46, Subpart
7 A, as amended from time to time.

8 (2) "Cloning of a human being" means inducing or permitting a
9 replicate of a living human being's complete set of genetic material to
10 develop into the stage of human development after the embryonic
11 stage when cells undergoing division are sufficiently differentiated
12 such that organ formation is observable.

13 (3) "Embryonic stem cells" means cells created through the joining of
14 a human egg and sperm or through nuclear transfer that are
15 sufficiently undifferentiated such that they cannot be identified as
16 components of any specialized cell type.

17 (4) "Nuclear transfer" means the replacement of the nucleus of a
18 human egg with a nucleus from another human cell.

19 (5) "Eligible institution" means (A) a nonprofit, tax-exempt academic
20 institution of higher education, (B) a hospital that conducts biomedical
21 research, or (C) any entity that conducts biomedical research or
22 embryonic or adult stem cell research.

23 (b) No person shall knowingly (1) engage or assist, directly or
24 indirectly, in the cloning of a human being, (2) implant human
25 embryos created by nuclear transfer into a uterus or a device similar to
26 a uterus, or (3) facilitate human reproduction through clinical or other
27 use of human embryos created by nuclear transfer. Any person who
28 violates the provisions of this subsection shall be fined not more than
29 one hundred thousand dollars or imprisoned not more than ten years,
30 or both. Each violation of this subsection shall be a separate and
31 distinct offense.

32 (c) (1) A physician or other health care provider who is treating a
33 patient for infertility shall provide the patient with timely, relevant
34 and appropriate information sufficient to allow that person to make an
35 informed and voluntary choice regarding the disposition of any
36 embryos or embryonic stem cells remaining following an infertility
37 treatment.

38 (2) A patient to whom information is provided pursuant to
39 subdivision (1) of this subsection shall be presented with the option of
40 storing, donating to another person, donating for research purposes, or
41 otherwise disposing of any unused embryos or embryonic stem cells.

42 (3) A person who elects to donate for research purposes any
43 embryos or embryonic stem cells remaining after receiving infertility

44 treatment shall provide written consent for that donation and shall not
45 receive monetary payment, direct or indirect, for such embryos or
46 embryonic stem cells.

47 (4) Any person who violates the provisions of this subsection shall
48 be fined not more than fifty thousand dollars or imprisoned not more
49 than five years, or both. Each violation of this subsection shall be a
50 separate and distinct offense.

51 (d) A person may conduct research involving embryonic stem cells,
52 provided (1) the research is conducted with full consideration for the
53 ethical and medical implications of such research, (2) prior to
54 conducting such research, the person provides to the Commissioner of
55 Public Health documentation verifying that any human embryos or
56 eggs used in such research have been donated voluntarily in
57 accordance with the provisions of subsection (c) of this section, (3) the
58 general research program under which such research is conducted is
59 reviewed and approved by an institutional review committee, as
60 required under federal law, and (4) the specific protocol used to derive
61 stem cells from an embryo is reviewed and approved by an
62 institutional review committee.

63 (e) The Commissioner of Public Health shall enforce the provisions
64 of this section and may adopt regulations, in accordance with the
65 provisions of chapter 54 of the general statutes, relating to the
66 administration and enforcement of this section. The commissioner may
67 request the Attorney General to petition the Superior Court for such
68 order as may be appropriate to enforce the provisions of this section.

69 Sec. 2. Section 19a-32c of the general statutes is repealed and the
70 following is substituted in lieu thereof (*Effective July 1, 2005*):

71 (a) There is created a Biomedical Research Trust Fund which shall
72 be a separate nonlapsing fund. The trust fund may accept transfers
73 from the Tobacco Settlement Fund and may apply for and accept gifts,
74 grants or donations from public or private sources to enable the
75 account to carry out its objectives. [On and after July 1, 2001, the] The

76 Commissioner of Public Health, in consultation with the Secretary of
77 the Office of Policy and Management, may make grants-in-aid from
78 the trust fund to eligible institutions for the purpose of funding
79 biomedical research in the fields of heart disease, cancer and other
80 tobacco-related diseases, and embryonic and adult stem cell research.
81 [For the fiscal year ending June 30, 2002, the total amount of such
82 grants-in-aid made during the fiscal year shall not exceed two million
83 dollars. For the fiscal year ending June 30, 2003, and each fiscal year
84 thereafter, the total amount of such grants-in-aid made during the
85 fiscal year shall not exceed fifty per cent of the total amount held in the
86 trust fund as of the date such grants-in-aid are approved. Not later
87 than April 1, 2001, the Commissioner of Public Health shall develop an
88 application for grants-in-aid under this section and may receive
89 applications from eligible institutions for such grants-in-aid on and
90 after said date. For purposes of this section, "eligible institution" means
91 (1) a nonprofit, tax-exempt academic institution of higher education, or
92 (2) a hospital that conducts biomedical research.]

93 (b) The Commissioner of Public Health shall develop an application
94 for grants-in-aid under this section and may receive applications from
95 eligible institutions for such grants-in-aid on and after July 1, 2005.

96 (c) For the fiscal year ending June 30, 2006, not less than ten million
97 dollars of the total amount held in the trust fund shall be made
98 available for grants-in-aid to eligible institutions for the purpose of
99 conducting embryonic or adult stem cell research, as directed by the
100 Stem Cell Research Advisory Committee established pursuant to
101 section 3 of this act.

102 (d) For the fiscal year ending June 30, 2007, not less than ten million
103 dollars of the total amount held in the trust fund shall be made
104 available for grants-in-aid to eligible institutions for the purpose of
105 conducting embryonic or adult stem cell research, as directed by the
106 Stem Cell Research Advisory Committee established pursuant to
107 section 3 of this act.

108 Sec. 3. (NEW) (*Effective from passage*) (a) There is established a Stem

109 Cell Research Advisory Committee. The committee shall consist of the
110 Commissioners of Public Health and Economic and Community
111 Development, or their designees, and eight members who shall serve
112 for a term of four years and shall be appointed as follows: Two by the
113 Governor; and one each by the president pro tempore of the Senate,
114 the speaker of the House of Representatives and the majority and
115 minority leaders of the Senate and House of Representatives. All
116 members appointed to the committee shall possess knowledge and
117 understanding of the field of stem cell research and shall work to
118 advance embryonic and adult stem cell research in Connecticut. All
119 appointments to the committee shall be made by November 1, 2005.
120 Any vacancy shall be filled by the appointing authority.

121 (b) The Commissioner of Public Health, or the commissioner's
122 designee, shall serve as the chairperson of the committee and shall
123 schedule the first meeting of the committee, which shall be held no
124 later than December 1, 2005.

125 (c) The Stem Cell Research Advisory Committee shall (1) direct the
126 Commissioner of Public Health with respect to the awarding of grants-
127 in-aid pursuant to section 19a-32c of the general statutes, as amended
128 by this act, to eligible institutions for the purpose of conducting
129 embryonic or adult stem cell research, and (2) monitor the stem cell
130 research conducted by eligible institutions that receive such grants-in-
131 aid.

132 (d) Not later than June 30, 2006, and annually thereafter, the Stem
133 Cell Research Advisory Committee shall report, in accordance with
134 section 11-4a of the general statutes, to the Governor and the General
135 Assembly on (1) the amount of grants-in-aid made pursuant to section
136 19a-32c of the general statutes, as amended by this act, for stem cell
137 research, (2) the recipients of such grants-in-aid, and (3) the current
138 status of stem cell research in the state.

139 (e) Not later than October 1, 2006, the Stem Cell Research Advisory
140 Committee shall submit recommendations to the Governor and the
141 joint standing committees of the General Assembly having cognizance

142 of matters relating to public health and appropriations and the budgets
143 of state agencies concerning the amount of funding necessary to
144 sustain embryonic and adult stem cell research in this state for the
145 biennium ending June 30, 2009.

146 Sec. 4. (NEW) (*Effective from passage*) (a) There is established a Stem
147 Cell Research Peer Review Committee. The committee shall consist of
148 five members appointed by the Commissioner of Public Health. All
149 members appointed to the committee shall have demonstrated
150 knowledge and understanding of the ethical and medical implications
151 of embryonic and adult stem cell research and shall work to advance
152 embryonic and adult stem cell research in Connecticut. All
153 appointments to the committee shall be made by November 1, 2005.

154 (b) Prior to the awarding of any grants-in-aid for embryonic or adult
155 stem cell research pursuant to section 19a-32c of the general statutes, as
156 amended by this act, the Stem Cell Research Peer Review Committee
157 shall review all applications submitted by eligible institutions for such
158 grants-in-aid and make recommendations to the Commissioner of
159 Public Health and the Stem Cell Research Advisory Committee with
160 respect to the ethical and scientific merit of each application.

161 (c) The Commissioner of Public Health may adopt regulations, in
162 accordance with the provisions of chapter 54 of the general statutes,
163 setting forth guidelines for the rating and scoring of such applications
164 by the Stem Cell Research Peer Review Committee.

165 Sec. 5. (*Effective July 1, 2005*) The sum of ten million dollars is
166 appropriated to the Biomedical Research Trust Fund, from the General
167 Fund, for the fiscal year ending June 30, 2006, for embryonic and adult
168 stem cell research.

169 Sec. 6. (*Effective July 1, 2006*) The sum of ten million dollars is
170 appropriated to the Biomedical Research Trust Fund, from the General
171 Fund, for the fiscal year ending June 30, 2007, for embryonic and adult
172 stem cell research.

This act shall take effect as follows and shall amend the following sections:

Section 1	<i>October 1, 2005</i>	New section
Sec. 2	<i>July 1, 2005</i>	19a-32c
Sec. 3	<i>from passage</i>	New section
Sec. 4	<i>from passage</i>	New section
Sec. 5	<i>July 1, 2005</i>	New section
Sec. 6	<i>July 1, 2006</i>	New section

PH *Joint Favorable Subst. C/R*

JUD

JUD *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 06 \$	FY 07 \$
Public Health, Dept.	GF - Cost	10,000,000	10,000,000
Public Health, Dept.	BRTF	See Below	See Below
Judicial Dept. (Probation); Correction, Dept.	GF - Cost	Potential Minimal	Potential Minimal
Judicial Dept.	GF - Revenue Gain	Potential	Potential
Attorney General	GF - None	None	None
Department of Economic & Community Development	GF - None	None	None
Policy & Mgmt., Off.	GF - None	None	None
UConn Health Ctr.	GF	See Below	See Below

Note: GF=General Fund d BRTF= Biomedical Research Trust Fund

Municipal Impact: None

Explanation

This bill makes various changes concerning stem cell research and related topics and results in fiscal impacts as follows:

Section 1 of the bill makes it a crime to engage in certain activities related to the cloning of a human being or the creation of a human embryo by nuclear transfer. The bill would subject an offender to a fine of up to \$100,000, imprisonment for up to ten years, or both.

To the extent that offenders are subject to incarceration or probation supervision in the community as a result of the bill, a potential cost to criminal justice agencies exists. On average, it costs the state \$2,150 to supervise an offender on probation in the community as compared to \$35,040 to incarcerate the offender (note that both figures include fringe benefits).

It is anticipated that the Department of Public Health will be able to

adopt the required regulations and pursue enforcement actions without requiring additional resources. The Office of the Attorney General and the Judicial Department will be able to accommodate any workload increase within each agency's anticipated budgetary resources.

Section 2 requires the Commissioner of Public Health to award grants-in-aid of up to \$10 million in each of FY 06 and FY 07 from the Biomedical Research Trust Fund (BRTF) for embryonic and adult stem cell research. Additionally, it requires the Office of Policy and Management to consult with the department concerning any grant-in-aid made from the BRTF. It is expected that each agency can accommodate these requirements within their respective anticipated budgetary resources.

The University of Connecticut Health Center would be eligible to apply for and receive these funds under the bill's definition of an eligible institution.

This section also eliminates a requirement of current law that limits the expenditures from the BRTF to fifty percent of the amount held in the Trust Fund on the date grants-in-aid are approved. Pursuant to Section 4-28b(c)(2) CGS, the sum of \$4 million is transferred from the Tobacco Settlement Fund to the BRTF annually.

Section 3 creates a Stem Cell Research Advisory Committee. It is anticipated that the DPH and the Department of Economic and Community Development will be able to participate in the activities of the committee without requiring additional resources.

Section 4 creates a Stem Cell Research Peer Review Committee. Should the DPH adopt regulations concerning guidelines to be used by the Committee when scoring grant applications, it is anticipated that it can do so without requiring additional resources.

Sections 5 and 6 appropriate \$10 million in each of FY 06 and FY 07 from the General Fund to the Biomedical Research Trust Fund for

embryonic and adult stem cell research. sHB 6671, the FY 06-07 Biennial Budget (as favorably reported by the Appropriations Committee) does not appropriate any General Fund dollars in either FY 06 or FY 07 for this purpose.

OLR Bill Analysis

sSB 934

***AN ACT PERMITTING STEM CELL RESEARCH AND BANNING
THE CLONING OF HUMAN BEINGS*****SUMMARY:**

This bill permits research in the state involving human embryonic stem cells if (1) the research is conducted with full consideration of its medical and ethical implications; (2) before beginning the research, the researcher documents to the public health commissioner that any human embryos or eggs used were donated voluntarily; (3) the general research program under which the stem cell research is conducted is reviewed and approved by an institutional review committee as required by federal law; and (4) the specific protocol used to derive stem cells from an embryo is reviewed and approved by an institutional review committee.

The bill also:

1. requires physicians or other health care providers treating a patient for infertility to provide her with timely, relevant, and appropriate information sufficient to allow her to make an informed and voluntary choice about the disposition of any embryos or embryonic stem cells remaining after an infertility treatment;
2. prohibits a person from knowingly (a) engaging or assisting, directly or indirectly, in the cloning of a human being, (b) implanting human embryos created by nuclear transfer into a uterus or device similar to a uterus ("nuclear transfer" means replacing the nucleus of a human egg with the nucleus from another human cell); and (c) facilitating human reproduction through clinical or other use of human embryos created by nuclear transfer (violation of any of these provisions results in a fine of up to \$100,000, imprisonment up to 10 years, or both, with each violation a separate offense);

3. requires the Department of Public Health (DPH) to enforce the bill's provisions, allows the commissioner to adopt regulations to administer and enforce it, and allows him to ask the attorney general to petition the Superior Court for an appropriate order to enforce it;
4. makes \$10 million per year from the Biomedical Research Trust Fund available in FYs 2006 and 2007 for grants-in-aid to eligible institutions for embryonic or adult stem cell research;
5. establishes a 10-member Stem Cell Research Advisory Committee responsible for (a) directing the DPH commissioner in awarding research grants and (b) monitoring research conducted by the institutions receiving them; and
6. establishes a five-member Stem Cell Research Peer Review Committee responsible for reviewing all grant applications and making recommendations to DPH and the advisory committee on the ethical and scientific merit of each application.

EFFECTIVE DATE: October 1, 2005, except for (1) the provision directing the Biomedical Research Trust Fund to fund stem cell research which takes effect July 1, 2005; (2) the provisions creating the research advisory and peer review committees, which take effect upon passage; (3) the \$10 million appropriation for FY 2006, which takes effect July 1, 2005; and (4) the \$10 million appropriation for FY 2007, which takes effect July 1, 2006.

EMBRYONIC STEM CELLS

The bill defines embryonic stem cells as cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated so that they cannot be identified as components of any specialized cell type.

INSTITUTIONAL REVIEW COMMITTEE

Under the bill, an institutional review committee is the local institutional review committee established according to federal law to supervise the clinical testing of devices in facilities where proposed clinical testing is to be conducted. The bill also refers to an "institutional review board" (IRB), which is responsible for ensuring

that human subjects engaged in research are treated with dignity, are protected from harm, and have given informed consent to participation in research. An IRB reviews and approves research protocols before any work is started and reviews ongoing research periodically to ensure the protection of subjects.

CLONING OF A HUMAN BEING

The bill defines cloning of a human being as inducing or permitting a replicate of a living human being's complete set of genetic material to develop into the stage of human development after the embryonic stage when cells undergoing division are sufficiently differentiated so that organ formation is observable.

PATIENTS UNDERGOING FERTILITY TREATMENT

Under the bill, a patient undergoing infertility treatment who receives the required information on the disposition of remaining human embryos or embryonic stem cells must be given the option of storing them, donating them to another person, donating them for research purposes, or otherwise disposing of them. People choosing donation for research purposes must give written consent for the donation and cannot receive any direct or indirect monetary payment for them.

Anyone violating these provisions is subject to a fine of up to \$50,000, a prison term of up to five years, or both. Each violation is a separate offense.

BIOMEDICAL RESEARCH TRUST FUND AND RESEARCH GRANTS

The bill allows the DPH commissioner, in consultation with Secretary of the Office of Policy and Management, to make grants-in-aid from the existing Biomedical Research Trust Fund to eligible institutions for embryonic and adult stem cell research. Currently, this fund can accept transfers from the Tobacco Settlement Fund and may apply for and accept gifts, grants, or donations from public and private sources in order to make grants to eligible institutions to fund biomedical research in heart disease, cancer, and other tobacco-related diseases. An "eligible institution" is (1) a nonprofit, tax-exempt academic institution of higher education; (2) a hospital conducting biomedical research; or (3) any entity conducting biomedical research or embryonic or adult stem cell research.

The bill requires the DPH commissioner to develop an application for the grants and allows DPH to take applications beginning July 1, 2005.

Under the bill, at least \$10 million of the amount in the trust fund must be made available in FY 2006 for grants to eligible institutions for embryonic and adult stem cell research. The same standard applies to FY 2007.

The bill appropriates \$20 million in total to the Biomedical Research Trust Fund from the General Fund for embryonic and adult stem cell research; \$10 million in FY 2006 and \$10 million in FY 2007.

STEM CELL RESEARCH ADVISORY COMMITTEE

This 10-member committee includes the public health and economic and community development commissioners, or their designees, and eight members appointed as follows: two by the governor, and one each by the Senate president pro tempore, House speaker, and the majority and minority leaders of the Senate and House. The eight appointed members serve four-year terms and all must have knowledge and understanding of stem cell research and work to advance it in Connecticut. All appointments must be made by November 1, 2005. The DPH commissioner or his designee is the committee's chair. The first meeting must be held by December 1, 2005.

Under the bill, the advisory committee must direct the DPH commissioner in awarding grants and monitoring stem cell research by the institutions receiving grants. By June 30, 2006 and annually thereafter, the advisory committee must report to the governor and General Assembly on the amount of grants made, grant recipients, and the status of stem cell research in the state. By October 1, 2006, the committee must make recommendations to the governor and the Public Health and Appropriations committees on the amount of funding necessary to sustain the research for the biennium ending June 30, 2009.

STEM CELL RESEARCH PEER REVIEW COMMITTEE

The bill requires the DPH commissioner to appoint the five members of this body. All members must have demonstrated knowledge and understanding of the ethical and medical implications of embryonic

and stem cell research and work to advance it in the state. All appointments must be made by November 1, 2005.

Before any grants are awarded (see above), the peer review committee must review all applications submitted by eligible institutions and make recommendations to the DPH commissioner and the research advisory committee concerning the ethical and scientific merit of each application.

The bill allows the DPH commissioner to adopt regulations on guidelines for rating and scoring the applications.

BACKGROUND

Related Bill

sHB 5912, "An Act Promoting Stem Cell Research in the State," establishes a Connecticut Advanced Cell Advisory Council to analyze, improve, and promote stem cell research in Connecticut. It also establishes a Stem Cell Research Fund to be managed by Connecticut Innovations, Inc. The bill has received favorable reports from the Commerce and Judiciary committees.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute Change of Reference

Yea 18 Nay 5

Judiciary Committee

Joint Favorable Report

Yea 28 Nay 8